

### **REMARKS**

Upon entry of the foregoing amendments, claims 1-23 will remain pending, where claims 1, 2 and 19 are independent claims.

#### **Explanation of the Amendments**

Claims 10-14, 18 and 20 have been amended by changing “said” to “the” for the sake of consistency throughout the claims.

Claims 22 was amended to change the style of the claim from a “use” claim to a claim for a method of use of the estrogen receptor gene of claim 1 for measuring the ability of a test substance to regulate estrogen receptor activity. Claim 23 also has been amended to change the style of the claim from a “use” claim to a claim for a method of use of a ligand binding domain of an estrogen receptor gene of claim 1. The method of claims 22 and 23 is a method for measuring the ability of a test substance to regulate estrogen receptor activity. The language used in method claims 22 and 23 is supported at least by the explanation of the method at pages 43-51 in the application as originally filed. No new matter has been added and no narrowing of the claims has been done by the amendments. Accordingly, entry of the foregoing amendments is respectfully solicited.

#### **Response to Restriction and Election Requirements**

Other than pointing out that claims 22 and 23 were “use” claims, the outstanding Office Action contains only a restriction requirement among four groups of claims Group I–IV, and an election requirement among three identified species within each Group.

Applicant respectfully traverses the restriction requirement.

The Examiner alleges that claim 1 of Group I is drawn to “numerous nucleotide sequences, each coding an amino acid sequence comprising a polypeptide of unique structural and functional characteristics. Since the first claimed invention does not recite a single special technical feature, it cannot share a special technical feature with the Inventions of Group II-IV”.

Applicant respectfully disagrees. SEQ ID NO:1, SEQ ID NO:4 and SEQ ID NO:23, each represents an amino acid sequence for a bluegill estrogen receptor, *i.e.*, bluegill estrogen receptor alpha 1 (BGER $\alpha$ 1), bluegill estrogen receptor alpha 2 (BGER $\alpha$ 2), and bluegill estrogen receptor

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Claims 22 was amended to change the style of the claim from a “use” claim to a claim for a method of use of the estrogen receptor gene of claim 1 for measuring the ability of a test substance to regulate estrogen receptor activity. Claim 23 also has been amended to change the style of the claim from a “use” claim to a claim for a method of use of a ligand binding domain of an estrogen receptor gene of claim 1. The method of claims 22 and 23 is a method for measuring the ability of a test substance to regulate estrogen receptor activity. The language used in method claims 22 and 23 is supported at least by the explanation of the method at pages 43-51 in the application as originally filed. No new matter has been added and no narrowing of the claims has been done by the amendments. Accordingly, entry of the foregoing amendments is respectfully solicited.

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Applicant respectfully traverses the restriction requirement.

The Examiner alleges that claim 1 of Group I is drawn to “numerous nucleotide sequences, each coding an amino acid sequence comprising a polypeptide of unique structural and functional characteristics. Since the first claimed invention does not recite a single special technical feature, it cannot share a special technical feature with the Inventions of Group II-IV”.

Applicant respectfully disagrees. SEQ ID NO:1, SEQ ID NO:4 and SEQ ID NO:23, each represents an amino acid sequence for a bluegill estrogen receptor, *i.e.*, bluegill estrogen receptor alpha 1 (BGER $\alpha$ 1), bluegill estrogen receptor alpha 2 (BGER $\alpha$ 2), and bluegill estrogen receptor

beta (BGER $\beta$ ), respectively. Therefore, the several nucleotide sequences of claim 1 share a special technical feature in that each of the nucleotide sequences encodes for an amino acid sequence that is either identical to or shares significant sequence identity with an estrogen receptor from bluegill fish.

Groups II and IV contain process of use claims that are not separate and distinct from Group I. The process claims 20 of Group II and 22-23 of Group IV cannot be performed using a different nucleic acid other than that based on claim 1 of Group I because of the reference to the sequence of claim 1 in the claims. The receptor binding assay of claim 21, of Group III, in essence a process claim, cannot be performed using a different estrogen receptor other than that based on claim 19 of Group I because of the reference in claim 21 to the estrogen receptor of claim 19. Therefore, the relationship between the groups is such that they should not be considered separate and distinct.

For the above reasons, the restriction requirement is improper, and reconsideration and withdrawal of the restriction requirement regarding different inventions are respectfully solicited.

Applicant hereby also traverses the election of species requirements. The Examiner has required an election of Species A to C if any of the Inventions in Groups I, II or IV are elected and an election of Species 1 to 3 if the Invention of Group III is elected. Species A to C each recites a coding region of a nucleotide sequence, SEQ ID NO:2, SEQ ID NO:5 or SEQ ID NO:24, respectively, that encodes an amino acid sequence SEQ ID NO:1, SEQ ID NO:4 or SEQ ID NO:23, respectively. Species 1 to 3 each recites an amino acid sequence SEQ ID NO:1, SEQ ID NO:4 or SEQ ID NO:23, respectively. Applicant respectfully submits that Species A to C share special technical features as each was derived from the bluegill species of fish and encodes an amino acid sequence for a bluegill estrogen receptor. Similarly, Applicant respectfully submits that Species 1 to 3 share special technical features as each represents an amino acid sequence for a bluegill estrogen receptor. Applicant respectfully submits that searching and examining Species A to C or Species 1 to 3 will not constitute a serious burden. Reconsideration and withdrawal of the election of species requirement are respectfully solicited.

At least, Applicant respectfully requests the Examiner to include in each Species A to C, respectively, the genus of nucleotide sequences that encode an amino acid sequence SEQ ID NO:1, SEQ ID NO:4 or SEQ ID NO:23, because one skilled in the art could readily envision all

the nucleotide sequences degenerate to SEQ ID NO:2, SEQ ID NO:5, or SEQ ID NO:24, by using a genetic code table. Applicant further respectfully requests the Examiner at least to include in each Species A to C, respectively, the genus of nucleotide sequences that encode an amino acid sequence exhibiting at least about 95% sequence identity to SEQ ID NO:1, at least about 95% sequence identity SEQ ID NO:4, or at least about 85% sequence identity to SEQ ID NO:23, because one skilled in the art could readily envision such nucleotide sequences by using a genetic code table, protein homology alignment, and other molecular biology tools. For similar reasons, Applicant respectfully requests the Examiner to at least include in each Species 1 to 3, respectively, the genus of amino acid sequences exhibiting at least about 95% sequence identity to SEQ ID NO:1, at least about 95% sequence identity SEQ ID NO:4, or at least about 85% sequence identity to SEQ ID NO:23.

Applicant also points out that a reasonable and small number of species are present, and respectfully requests that all species be considered in this application.

In the event that the Examiner maintains the restriction requirement, Applicant provisionally elects Group I (claims 1-19) for initial examination in this application. In the event that the Examiner maintains the election of species requirement, Applicant provisionally elects the Species that recites SEQ ID NO:4, *i.e.*, Species B for Group I, II, or IV (identified by the Examiner as nucleotides 74-1819 of SEQ ID NO: 5 encoding amino acid SEQ ID NO: 4), or Species 2 for Group III (identified by the Examiner as the amino acid sequence of SEQ ID NO:4). For the reasons discussed above, the provisional elections of Invention Groups and Species are made with traverse.

In view of the dependency of claims 20, 22 and 23 from claim 1, and the dependency of claim 21 from claim 19, both of which are in provisionally elected Group I, Applicant respectfully submits that all of claims 1-23 read on the elected Invention Group I, and claims 1-20 and 22-23 read on the elected Species Group B.

The Office Action noted at page 5 that where restriction has been made, as here, between product and process claims, and where Applicant has elected the product claims, as done here, then the process claims that depend from or otherwise include all of the elements and aspects of the product claims will be considered for rejoinder upon a finding that the product claims are allowable. Accordingly, Applicant respectfully requests the Examiner to rejoin the process

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claims 20 of Group II and 22-23 of Group IV when the product claim 1 of Group I is found to be allowable, and to rejoin the process claim 21 of Group III when the product claim 19 of Group I is found to be allowable.

Reconsideration and an early substantive examination of all of the claims in the application are respectfully solicited.

Respectfully submitted,

**KOICHI SAITO**

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(Date)

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